JUL 1 3 2001

K011401

510(K) Summary

Rambler Mobility Inc.
510(K) Premarket Notification
Rambler

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Rambler Mobility Inc.
1401 Old Elkton Dr.
Forest, VA 24551
Phone: (804) 525-1544
Fax: (804) 525-3733

Contact Person: Joel Husted
Date Prepared: 05/3/01

Proprietary Name of Device: Rambler

Common Name: 3-wheeled scooter

Classification Name: Vehicle, Motorized 3-wheeled

Identification of the predicate device:

510(k) number k931231, the Pride Sidekick II model 3-wheeled scooter

Description of the device:

The Rambler is a 3-wheeled scooter. It is light-weight and portable. Right and left hand levers independently control the rear wheels to make it stop, start and turn. It can also optionally be controlled by a walking assistant from behind the device.

Intended use:

The Rambler is intended to provide mobility to those who would otherwise be bed or chair confined but have moderate abilities in both upper limbs.

Comparison to Predicate Device:

The Rambler device is deemed to be substantially equivalent in use, capability and intention to the predicate device. Both devices are of the 3-wheeled variety and share similar dimensional qualities. Both devices utilize a 24 volt electrical system and deliver similar performance characteristics. They also both share substantially the same intended usage.

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Discussion of non-clinical testing:

The following tests were carried out by qualified personnel under controlled conditions at the Rambler facility. Results are disclosed in the attached submission.

Determination of Braking Effectiveness
Determination of Static Stability
Determination of Dynamic Stability at Maximum Speed
Determination of Maximum Range and Speed
Determination of Obstacle Climbing Ability
Determination of Maximum Hill Climb Capacity

No clinical testing has been performed.

Conclusion drawn from test results:

The Rambler benefits from extreme electrical and mechanical design simplicity resulting in superior reliability, durability and including immunity to EMI concerns. Test results proved satisfactory or superior to industry standards with respect to performance characteristics including maneuverability, stability and braking effectiveness. In all due considerations of the testing here performed the Rambler proves to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 3 2001

Mr. Joel Husted
Vice-President
Rambler Mobility Inc.
1401 Old Elkton Drive
Forest, Virginia 24551

Re: K011401
Trade Name: Rambler
Regulation Number: 890.3800
Regulatory Class: Class II
Product Code: INI
Dated: May 23, 2001
Received: March 29, 2001

Dear Mr. Husted:

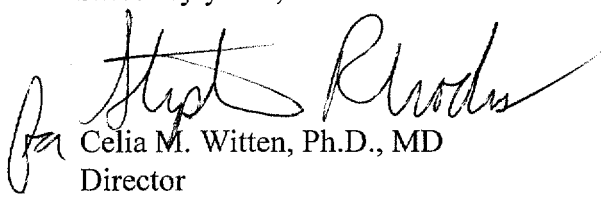
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011401

Device Name: Rambler

Indications For Use:

The Rambler is intended to provide mobility to those who would otherwise be bed or chair confined but have moderate abilities in both upper limbs.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011401

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)